Louisiana Office of Public Health Laboratories	
Test Name	Hepatitis A IgG and IgM Antibody EIA
PHL Location	Office of Public Health Laboratory Baton Rouge
CPT Code	86708
Synonyms	Total Antibodies to Hepatitis A Virus, Anti-HAV Total (IgG and IgM)
Brief Description of Test	The MONOLISA™ Anti-HAV EIA is an in vitro enzyme immunoassay for use in the qualitative detection of total antibodies (IgG and IgM) to hepatitis A virus (anti-HAV) in human (adult and pediatric) serum. This assay is indicated as an aid in the diagnosis of acute or past hepatitis A virus (HAV) infection or as an aid in the identification of HAV-susceptible individuals for vaccination.
Possible Results	Nonreactive Borderline Reactive
Reference Range	Nonreactive
Specimen Type	Serum
Specimen Container(s):	Red top tubes, Marble top tubes, polypropylene vials
Minimum volume accepted:	250 µL serum (does not allow for repeat testing)
Collection Instructions	Specimens should only be collected by personnel that have been properly trained. Care should be taken during specimen collection and handling to avoid generation of aerosols. Blood should be collected in a plastic tube, such as a vacutainer, which does not contain an anticoagulant. The collection tube may or may not contain a serum separator. If collected in a tube without serum separator, serum must be aliquoted into screw cap tubes before shipment to laboratory. Depending on the type of collection tube, the amount of time it will take for the blood to clot could take up to 60 minutes. Separation of serum from cells should take place within 2 hours of collection to prevent erroneous test results according to NCCLS guidelines. Follow the package insert for the collection tube you use. Label specimen with Patient Name and a 2nd unique identifier such as a chart number or medical record number. DOB is not considered unique.

	Complete a Lab Form 96 to accompany the serum sample. Lab submission form must be thoroughly completed with patient's first and last name, 2nd patient identifier, gender, date of birth, date of collection, time of collection, test requested, and submitter's name, address, and contact number. Two unique identifiers **MUST** be recorded on the tube **AND** the Lab 96 form. A missing identifier on the tube will be an automatic rejection. If the identifiers are missing from the Lab 96 form, the submitter must be contacted and a new form with this information must be faxed back to the lab before testing will take place. Transport specimen to laboratory as soon as possible after collection. Keep submission forms insulated from specimens.
Storage and Transport Instructions	Specimens must be shipped refrigerated (2-8°C) and can be stored for up to 7 days. For longer storage, serum should be poured into a sterile screw cap tube and be frozen at -20°C or colder. Frozen specimens must be shipped on dry ice and received at a temperature of -20°C or colder. If samples are frozen, document the date and time the sample was frozen.
Causes for Rejection	Unspun samples, tubes that contain less than 90% of the total drawing capacity (QNS), incorrect specimen type, or expired collection tubes must be rejected. Hyperhemolyzed specimens, contaminated specimens, hyperlipemic specimens, improper storage and improper transport temperature requirements are also reasons for rejection.
Limitations of the Procedure	Diagnosis of an infectious disease should not be established on the basis of a single test result. Any diagnosis should take into consideration the patient's clinical history and symptoms, as well as other laboratory data. The assay calibrator is equivalent to 20mIU/mL standardized to the WHO 2nd Reference Standard for Anti-hepatitis Immunoglobulin. However, assay results cannot be considered quantitative and no clinical claims for immunity can be determined from the cutoff. A reactive anti-HAV result does not exclude co-infection by another hepatitis virus. The nonreactive result does not exclude the possibility of infection with hepatitis A virus. Levels of Anti-HAV may be below the cutoff in early infection. The performance of the MONOLISA™ Anti-HAV EIA has not been established with immunosuppressed or immunocompromised patients, cord blood, neonatal specimens, cadaveric specimens, heat-inactivated specimens, or body fluids other than serum or plasma, such as saliva, urine, amniotic, or pleural fluids. The MONOLISA™ Anti-HAV EIA detects both anti-HAV IgG and IgM antibodies. However, assays detecting total antibodies are known to be more sensitive for anti-IgG than IgM.

Interfering Substances	Heterophilic antibodies, bacterial contamination, hyperhemolysis, hyperlipemia
References	BioRad MONOLISA™ Anti-HAV EIA Package Insert. EVOLIS™ Operator Manual
Additional Information	None
Release Date	03/15/2016
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